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in the eye, for example, as measured by split-lamp techniques to monitor the composition in the eye for phase separation. Such rapid break down of the emulsion in the eye reduces vision distortion as the result of the presence of the emulsion in the eye, as well as facilitating the therapeutic effectiveness of the composition in treating dry eye disease.

Using reduced amounts of cyclosporin A, as in Composition II, to achieve therapeutic effectiveness mitigates even further against undesirable side effects and potential drug interactions. Prescribing physicians can provide (prescribe) Composition II to more patients and/or with fewer restrictions and/or with reduced risk of the occurrence of adverse events, e.g., side effects, drug interactions and the like, relative to providing Composition I.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims.

What is claimed is:

1. A method of treating dry eye disease, the method comprising topically administering to a human eye in need thereof a first topical ophthalmic emulsion at a frequency of twice a day, wherein the first topical ophthalmic emulsion comprises cyclosporin A in an amount of about 0.05% by weight, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer, water, and castor oil in an amount of about 1.25% by weight;

wherein the method is therapeutically effective in treating dry eye disease;

wherein the method provides overall efficacy substantially equal to administration of a second topical ophthalmic emulsion to a human eye in need thereof at a frequency of twice a day, the second emulsion comprising cyclosporin A in an amount of about 0.1% by weight and castor oil in an amount of about 1.25% by weight; and wherein the method results in substantially no detectable concentration of cyclosporin A in the blood of the human.

2. The method of claim 1, wherein the first topical ophthalmic emulsion further comprises a tonicity agent or a demulcent component.

3. The method of claim 2, wherein the tonicity agent or the demulcent component is glycerine.

4. The method of claim 1, wherein the first topical ophthalmic emulsion further comprises a buffer.

5. The method of claim 4, wherein the buffer is sodium hydroxide.

6. The method of claim 1, wherein the first topical ophthalmic emulsion further comprises glycerine and a buffer.

7. The method of claim 1, wherein the first topical ophthalmic emulsion comprises polysorbate 80 in an amount of about 1.0% by weight.

8. The method of claim 1, wherein the first topical ophthalmic emulsion comprises acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight.

9. The method of claim 1, wherein the first topical ophthalmic emulsion further comprises glycerine in an amount of about 2.2% by weight and a buffer.

10. The method of claim 9, wherein the buffer is sodium hydroxide.

11. The method of claim 2, wherein the first topical ophthalmic emulsion has a pH in the range of about 7.2 to about 7.6.

12. The method of claim 1, wherein substantially no detectable concentration of cyclosporin A in the blood of the human means that the concentration of cyclosporin A in the blood of the human is less than about 0.1 ng/ml.

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13. A method of enhancing tearing in a human eye, the method comprising topically administering to a human eye in need thereof a first topical ophthalmic emulsion at a frequency of twice a day, wherein the first topical ophthalmic emulsion comprises cyclosporin A in an amount of about 0.05% by weight, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer, water, and castor oil in an amount of about 1.25% by weight;

wherein the method is therapeutically effective in treating dry eye disease and wherein the method achieves at least as much therapeutic efficacy as administration of a second topical ophthalmic emulsion to a human eye in need thereof at a frequency of twice a day, the second emulsion comprising cyclosporin A in an amount of about 0.1% by weight and castor oil in an amount of about 1.25% by weight; and

wherein the method results in a concentration of cyclosporin A in the blood of the human of less than about 0.1 ng/ml.

14. The method of claim 13, wherein the first topical ophthalmic emulsion comprises acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight, polysorbate 80 in an amount of about 1.0% by weight, and wherein the first topical ophthalmic emulsion further comprises glycerine in an amount of about 2.2% by weight and a buffer.

15. The method of claim 14, wherein the first topical ophthalmic emulsion has a pH in the range of about 7.2 to about 7.6.

16. The method of claim 13, wherein the method is effective in enhancing lacrimal gland tearing.

17. A method of treating dry eye disease, the method comprising topically administering to a human eye in need thereof a first topical ophthalmic emulsion at a frequency of twice a day, wherein the first topical ophthalmic emulsion comprises cyclosporin A in an amount of about 0.05% by weight, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer, water, and castor oil in an amount of about 1.25% by weight; and

wherein the first topical ophthalmic emulsion breaks down more quickly in the human eye, once administered to the human eye, thereby reducing vision distortion in the human eye as compared to a second topical ophthalmic emulsion that contains only about 50% as much castor oil as the first topical ophthalmic emulsion.

18. The method of claim 17, wherein the first topical ophthalmic emulsion comprises acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight, polysorbate 80 in an amount of about 1.0% by weight, and wherein the first topical ophthalmic emulsion further comprises glycerine in an amount of about 2.2% by weight and a buffer.

19. The method of claim 18, wherein the first topical ophthalmic emulsion has a pH in the range of about 7.2 to about 7.6.

20. The method of claim 19, wherein the method results in a concentration of cyclosporin A in the blood of the human of less than about 0.1 ng/ml.

21. A method of restoring tearing, the method comprising topically administering to a human eye in need thereof a first topical ophthalmic emulsion at a frequency of twice a day, wherein the first topical ophthalmic emulsion comprises cyclosporin A in an amount of about 0.05% by weight, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer, water, and castor oil in an amount of about 1.25% by weight;